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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/786,445
				Filing Date	February 25, 2004
				First Named Inventor	Rodney A. Welch
				Group Art Unit	1652
				Examiner Name	Unknown /Tekchand Saidha/
				Attorney Docket Number	096429-9141
				Confirmation Number	5346
Sheet	1	of	6		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

TS	AA	Bauer, M. E. & Welch, R. A. (1996) "Characterization of an RTX Toxin from Enterohemorrhagic <i>Escherichia coli</i> O157:H" <i>Infect. Immun.</i> 64(1):167-175.
TS	AB	Bergamaschini, L., G. Gobbo, S. Gatti, L. Caccamo, P. Prato, M. Maggioni, P. Braidotti, R. Di Stefano, and L.R. Fassati. (2001) "Endothelial targeting with C1-inhibitor reduces complement activation in vitro and during ex vivo reperfusion of pig liver" <i>Clin Exp Immunol</i> 126:412-420.
TS	AC	Berggard, K., E. Johnsson, E. Morfeldt, J. Persson, M. Stalhammar-Carlemalm, and G. Lindahl. (2001) Binding of human C4BP to the hypervariable region of M protein: a molecular mechanism of phagocytosis resistance in <i>Streptococcus pyogenes</i> . <i>Mol Microbiol</i> 42(2):539-551
TS	AD	Boucher, R.C. (2002) "An overview of the pathogenesis of cystic fibrosis lung disease" <i>Advanced Drug Delivery Reviews</i> , 54:1359-1371.
TS	AE	Burland, V., Shao, Y., Perna, N. T., Plunkett, G., Sofia, H. J. & Blattner, F. R. (1998) "The complete DNA sequence and analysis of the large virulence plasmid of <i>Escherichia coli</i> O157:H7" <i>Nucleic Acids Research</i> 26(18):4196-4204.
TS	AF	Burland, V., Shao, Y., Perna, N. T., Plunkett, G., Sofia, H. J. & Blattner, F. R. Accession T42131; T00210 (03 Dec 1999 # Sequence_revision; 03 Dec 1999 # text_change 17 Nov 2002) <i>Nucleic Acids Research</i> 26:4196-4204.
TS	AG	Cai, S., and A.E. Davis, 3rd. (2003) "Complement regulatory protein C1 inhibitor binds to selectins and interferes with endothelial-leukocyte adhesion" <i>J Immunol</i> 171:4786-4791
TS	AH	Caldwell, E.E., A.M. Andreasen, M.A. Blietz, J.N. Serrahn, V. VanderNoot, Y. Park, G. Yu, R.J. Linhardt, and J.M. Weiler. (1999) "Heparin binding and augmentation of C1 inhibitor activity" <i>Arch Biochem Biophys</i> 361:215-222.
TS	AI	Caliezi, C., Wuillemin, W. A., Zeerleder, S., Redondo, M., Eisele, B. & Hack, C. E. (2000) C1-Esterase Inhibitor: An Anti-Inflammatory Agent and Its Potential Use in the Treatment of Diseases Other than Hereditary Angioedema" <i>Pharmacol. Rev.</i> 52(1):91-112.
TS	AJ	Caprioli, A., Luzzi, I., Gianviti, A., Russmann, H. & Karch, H. (1995) "Pheno-genotyping of verotoxin 2 (VT2)-producing <i>Escherichia coli</i> causing haemorrhagic colitis and haemolytic uraemic syndrom by direct analysis of patients' stools" <i>J. Med. Microbiol.</i> 43:348-353.
TS	AK	Catanese, J. & Kress, L. F. (1984) "Enzymatic Inactivation of Human Plasma C1-Inhibitor and a <sub>1</sub> - Antichymotrypsin by <i>Pseudomonas Aeruginosa</i> proteinase and Elastase" <i>Biochim. Biophys. Acta</i> 789:37-43.
TS	AL	Chan, J.Y., C.E. Burrowes, F.M. Habal, and H.Z. Movat. (1977) "The inhibition of activated factor XII (Hageman factor) by antithrombin III: the effect of other plasma proteinase inhibitors" <i>Biochim Biophys Res Commun</i> 74:150-158.

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TS	AM	Cooper, N.R. (1991) "Complement evasion strategies of microorganisms" <i>Immunol Today</i> 12:327-331.
TS	AN	Coutinho, M., K.S. Aulak, and A.E. Davis. (1994) "Functional analysis of the serpin domain of C1 inhibitor" <i>J Immunol</i> 153:3648-3654.
TS	AO	Datsenko and Warner (2000) "One-step inactivation of chromosomal genes in <i>Escherichia coli</i> K-12 using PCR products" <i>PNAS</i> 97(12) 6640-6645.
TS	AP	de Agostini, A., M. Schapira, Y.T. Wachtfogel, R.W. Colman, and S. Carrel. (1985) "Human plasma kallikrein and C1 inhibitor form a complex possessing an epitope that is not detectable on the parent molecules: demonstration using a monoclonal antibody" <i>Proc Natl Acad Sci U S A</i> 82:5190-5193.
TS	AQ	Dean-Nystrom, E, <i>et al.</i> (2002) "Vaccination of Pregnant Dams with Intimin O157 Protects Suckling Piglets from <i>Escherichia coli</i> O157:H7 Infection" <i>Infection and Immunity</i> . 70(5):2414-2418.
TS	AR	DeLoney, <i>et al.</i> (2002) "Role for Phosphoglucosyltransferase in <i>Vibrio fischeri</i> - <i>Euprymna scolopace</i> Symbiosis" <i>J. Bacteriology</i> , 184(18):5121-5129.
TS	AS	DeLorenzo, V. D. & Timmis, K. N. (1994) "Analysis and Construction of Stable Phenotypes in Gram-Negative Bacteria with Tn5-and Tn10- Derived Minitransposons" <i>Bacterial Pathogenesis</i> , eds. Clark, V. L. & Bavoil, P. M. (Academic Press, San Diego), 235:386-405.
TS	AT	Donnenberg, M.S. & Nataro, J.P. (1992) "Methods for Studying Adhesion of Diarrheagenic <i>Escherichia coli</i> " <i>Methods in Enzymology</i> , 253:324-327.
TS	AU	Elson, C. & Ealding, W. (1984) "Generalized Systemic and Mucosal Immunity in Mice after Mucosal Stimulation with Cholera Toxin" <i>Journal of Immunology</i> , 132(6):2736-2741.
TS	AV	Elson, C. & Ealding, W. (1984) "Cholera Toxin Feeding did not Induce Oral Tolerance in Mice and Abrogated Oral Tolerance to an Unrelated Protein" <i>Journal of Immunology</i> , 133(6):2892-2897.
TS	AW	Eriksson, K., <i>et al.</i> (2003) "Cholera Toxin and Its B Subunit Promote Dendritic Cell Vaccination with Different Influences on Th1 and Th2 Development" <i>Infection and Immunity</i> , 71(4):1740-1747.
TS	AX	Frank, M.M. (1992) "The mechanism by which microorganisms avoid complement attack" <i>Curr Opin Immunol</i> 4:14-19.
TS	AY	Frank, M.M., and L.F. Fries. (1989) "Complement. In Fundamental Immunology" W.E. Paul, editor. Raven Press, New York.
TS	AZ	Frankel, G., A.D. Phillips, I. Rosenshine, G. Dougan, J.B. Kaper, and S. Knutton. (1998) "Enteropathogenic and enterohaemorrhagic <i>Escherichia coli</i> : more subversive elements" <i>Mol Microbiol</i> 30(5):911-921.
TS	BA	Gadek, J. E., Hosea, S. W., Gelfand, J. A., Santaella, M., Wickerhauser, M.,

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TS		Triantaphyllopoulos, D. C. & Frank, M. M. (1980) "Replacement Therapy in Hereditary Angioedema" <i>N. Engl. J. Med.</i> 302(10):542-546.
TS	BB	Gigli, I., T. Fujita, and V. Nussenzweig. (1979) "Modulation of the classical pathway C3 convertase by plasma proteins C4 binding protein and C3b inactivator" <i>Proc Natl Acad Sci U S A</i> 76:6596-6600.
TS	BC	Harlow, E., and D. Lane. (1988) Antibodies: a laboratory manual. Cold Spring Harbor Laboratory Press, Cold Spring Harbor.
TS	BD	Hauert, J., P.A. Patston, and M. Schapira. (2000) "C1 inhibitor cross-linking by tissue transglutaminase" <i>J Biol Chem</i> 275(19):14558-14562.
TS	BE	Hellwage, J., T. Meri, T. Heikkila, A. Alitalo, J. Panelius, P. Lahdenne, I.J. Seppala, and S. Meri. (2001) "The complement regulator factor H binds to the surface protein OspE of <i>Borrelia burgdorferi</i> " <i>J Biol Chem</i> 276(11):8427-8435.
TS	BF	Hong, Y.Q., and B. Ghebrehiwet. (1992) "Effect of <i>Pseudomonas aeruginosa</i> elastase and alkaline protease on serum complement and isolated components C1q and C3" <i>Clin Immunol Immunopathol</i> 62:133-138.
TS	BG	Huntington, J.A., R.J. Read, and R.W. Carrell. (2000) "Structure of a serpin-protease complex shows inhibition by deformation" <i>Nature</i> 407:923-926.
TS	BH	Jiang, H., E. Wagner, H. Zhang, and M.M. Frank. (2001) "Complement 1 Inhibitor is a regulator of the alternative complement pathway" <i>J Exp Med</i> 194:1609-1616.
TS	BI	Jiang, W. & Bond, J. S. (1992) "Families of metalloendopeptidases and their relationship" <i>FEBS Lett</i> 312(2,3):110-114.
TS	BJ	Judge, N., et al. (2004) "Plant Cell-Based Intimin Vaccine Given Orally to Mice Primed with Intimin Reduces Time of <i>Escherichia coli</i> O157:H7 Shedding in Feces" <i>Infection and Immunity</i> , 72(1):168-175.
TS	BK	Jung, C.-M., Matsushita, O., Katayama, S., Minami, J., Sakurai, J. & Okabe, A. (1999) "Identification of Metal Ligands in the <i>Clostridium histolyticum</i> CohH Collagenase" <i>J. Bact.</i> 181(9):2816-2822.
TS	BL	Karmali, M. A., Petric, M., Steele, B. T. & Lim, C. (1983) "Sporadic Cases of Haemolytic-Uraemic Syndrom Associated with Faecal Cytotoxin and Cytotoxin-Producing <i>Escherichia Coli</i> in Stools" <i>Lancet</i> 1:619-620.
TS	BM	Knutton, S., et al. (1989) "Actin Accumulation at Sites of Bacterial Adhesion to Tissue Culture Cells: Basis of a New Diagnostic Test for Enteropathogenic and Enterohemorrhagic <i>Escherichia coli</i> " <i>Infection and Immunology</i> , 57:1290-1298.
TS	BN	Kuno, K., Terashima, Y. & Matsushima, K. (1999) "ADAMTS-1 Is an Active Metalloproteinase Associated with the Extracellular Matrix" <i>Journal of Biological Chemistry</i> 274(26):18821-6.
TS	BO	Lathem, et al., (2004) "Potentiation of C1 Esterase Inhibitor by StcE, a Metalloprotease Secreted by <i>Escherichia coli</i> O157:H7" <i>J. Exp. Med.</i> 199(8) 1077-1087.

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TS	BP	Lathem, W.W., T. Bergsbaken, S.E. Witowski, N.T. Perna, and R.A. Welch. (2003) "Acquisition of StcE, a C1 esterase inhibitor-specific metalloprotease, during the evolution of <i>Escherichia coli</i> O157:H7" <i>J Infect Dis</i> : in press.
TS	BQ	Lathem, W.W., T.E. Grys, S.E. Witowski, A.G. Torres, J.B. Kaper, P.I. Tarr, and R.A. Welch. (2002) "StcE, a metalloprotease secreted by <i>Escherichia coli</i> O157:H7, specifically cleaves C1 esterase inhibitor" <i>Mol Microbiol</i> 45(2):277-288.
TS	BR	Lee, G. <i>et al.</i> (1998) "Tau interacts with src-family non-receptor tyrosine kinases" <i>Journal of Cell Science</i> , 111:3167-3177.
TS	BS	Li, Y., <i>et al.</i> (2000) "Human Response to <i>Escherichia coli</i> O157:H7 Infection: Antibodies to Secreted Virulence Factors" <i>Infection and Immunity</i> , 68(9):5090-5095.
TS	BT	Makino, <i>et al.</i> , (1998) "Complete Nucleotide Sequences of 93-kb and 3.3-kb Plasmids of Enterohemorrhagic <i>Escherichia coli</i> O157PH7 Derived from Sakai Outbreak" <i>DNA Research</i> , 5, 1-9.
TS	BU	Matsunami, K., S. Miyagawa, M. Yamada, M. Yoshitatsu, and R. Shirakura. (2000) "A surface-bound form of human C1 esterase inhibitor improves xenograft rejection" <i>Transplantation</i> 69:749-755.
TS	BV	Mayer, M.M. (1961) <i>Experimental Immunochemistry</i> . E.A. Kabat and M.M. Mayer, editors. Thomas, Springfield, IL.
TS	BW	Minta, J.O. (1981) "The role of sialic acid in the functional activity and the hepatic clearance of C1-INH" <i>J Immunol</i> 126(1):245-249.
TS	BX	Molla, A., T. Akaike, and H. Maeda. (1989) "Inactivation of various proteinases inhibitors and the complement system in human plasma by the 56-kilodalton proteinase from <i>Serratia marcescens</i> " <i>Infect Immun</i> 57(6):1868-1871.
TS	BY	Nataro, J.P., and J.B. Kaper. (1998) "Diarrheagenic <i>Escherichia coli</i> " <i>Clin Microbiol Rev</i> 11(1):142-201.
TS	BZ	Oda, T., Y. Kojima, T. Akaike, S. Ijiri, A. Molla, and H. Maeda. (1990) "Inactivation of chemotactic activity of C5a by the serratial 56-kilodalton protease" <i>Infect Immun</i> 58(5):1269-1272.
TS	CA	O'Farrell, P. H. (1975) "High Resolution Two-Dimensional Electrophoresis of Proteins*" <i>J Biol Chem</i> 250(10):4007-21.
TS	CB	Paton, A.W., and J.C. Paton. (2002) "Reactivity of convalescent-phase hemolytic-uremic syndrome patient sera with the megaplasmid-encoded TagA protein of shiga toxigenic <i>Escherichia coli</i> O157" <i>J Clin Microbiol</i> 40(4):1395-1399.

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TS	CC	Patston, P.A., and M. Schapira. (1997) "Regulation of C1-inhibitor function by binding to type IV collagen and heparin" <i>Biochem Biophys Res Commun</i> 230:597-601.
TS	CD	Patston, P.A., M. Qi, J.A. Schifferli, and M. Schapira. (1995) "The effect of cleavage by a <i>Crotalus atrox</i> alpha-proteinase fraction on the properties of C1-inhibitor" <i>Toxicon</i> 33(1):53-61.
TS	CE	Pensky, J., and H.G. Schwick. (1969) "Human serum inhibitor of C'1 esterase: identity with alpha-2-neuraminoglycoprotein" <i>Science</i> 163(3868):698-699.
TS	CF	Perna, N. T., Plunkett III, G., Burland, V., Mau, B., Glasner, J. D., Rose, D. J., Kirkpatrick, H. A., Postal, G., Hackett, J., Klink, S., Boutin, A., Shao, Y., Miller, L., Grotbeck, E. J., Davis, N. W., Lim, A., Dimalanta, E. T., Potamousis, K. D., Apodaca, J., Anantharaman, T. S., Lin, J., Yen, G., Schwartz, D. C., Welch, R. A. & Blattner, F. R. (2001) "Genome sequence of enterohaemorrhagic <i>Escherichia coli</i> O157:H7" <i>Nature</i> 409: 529-533.
TS	CG	Pierce, N.F. (March 20, 1978) "The Role of Antigen Form and Function in the Primary and Secondary Intestinal Immune Responses to Cholera Toxin and Toxoid in Rats" <i>J. Exp. Med</i> , The Rockefeller University Press, 195-206.
TS	CH	Pixley, R.A., M. Schapira, and R.W. Colman. (1985) "The regulation of human factor XIIa by plasma proteinase inhibitors" <i>J Biol Chem</i> 260:1723-1729.
TS	CI	Plunkett, G., 3rd, D.J. Rose, T.J. Durfee, and F.R. Blattner. (1999) "Sequence of Shiga toxin 2 phage 933W from <i>Escherichia coli</i> O157:H7: Shiga toxin as a phage late-gene product" <i>J Bacteriol</i> 181(6):1767-1778.
TS	CJ	Potempa, J., E. Korzus, and J. Travis. (1994) "The serpin superfamily of proteinase inhibitors: structure, function and regulation" <i>J Biol Chem</i> 269(23):15957-15960.
TS	CK	Potter, A., et al. (2004) "Decreased shedding of <i>Escherichia coli</i> O157:H7 by cattle following vaccination with type III secreted proteins" <i>Vaccine</i> , 22:362-369.
TS	CL	Pouille, M., Burnouf-Radosevich, M. & Burnouf, T. (1994) "Large-scale preparation of highly purified human C1-inhibitor for therapeutic use" <i>Blood Coagulation &amp; Fibrinolysis</i> 5:543-9.
TS	CM	Roesch, P. L. & Blomfield, I. C. (1998) "Leucine alters the interaction of the leucine-responsive regulatory protein (Lrp) with the fim switch to stimulate site-specific recombination in <i>Escherichia coli</i> " <i>Molecular Microbiology</i> 27(4):751-61.
TS	CN	Schapira, M., C.F. Scott, and R.W. Colman. (1982) "Contribution of plasma protease inhibitors to the inactivation of kallikrein in plasma" <i>J Clin Invest</i> 69:462-468.
TS	CO	Schmaier, A.H., S. Amenta, T. Xiong, G.D. Heda, and A.M. Gewirtz. (1993) "Expression of platelet C1 inhibitor" <i>Blood</i> 82(2):465-474.
TS	CP	Schmaier, A.H., S.C. Murray, G.D. Heda, A. Farber, A. Kuo, K. McCrae, and D.B. Cines. (1989) "Synthesis and expression of C1 inhibitor by human umbilical vein endothelial cells*" <i>J Biol Chem</i> 264(30):18173-18179.
TS	CQ	Siegler, R.L., (1995) "The hemolytic uremic syndrome" <i>Pediatr Clin North Am</i> .

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TS		Dec;42(6):1505-29
TS	CR	Shreedhar, V., <i>et al.</i> , (2003) "Cholera Toxin Induces Migration of Dendritic Cells from the Subepithelial Dome Region to the T- and B-Cell Areas of Peyer's Patches" <i>Infection and Immunity</i> , 71(1):504-509.
TS	CS	Sim, R.B., A. Reboul, G.J. Arlaud, C.L. Villiers, and M.G. Colomb. (1979) "Interaction of I125-labelled complement subcomponents C1r and C1s with protease inhibitors in plasma" <i>FEBS Lett</i> 97(1):111-115.
TS	CT	Storm, D., J. Herz, P. Trinder, and M. Loos. (1997) "C1 inhibitor-C1s complexes are internalized and degraded by the low density lipoprotein receptor-related protein" <i>J Biol Chem</i> 272(49):31043-31050.
TS	CU	te Loo, D.M., L.A. Monnens, T.J. van Der Velden, M.A. Vermeer, F. Preyers, P.N. Demacker, L.P. van Den Heuvel, and V.W. van Hinsbergh. (2000) "Binding and transfer of verocytotoxin by polymorphonuclear leukocytes in hemolytic uremic syndrome" <i>Blood</i> 95(11):3396-3402.
TS	CV	te Loo, D.M., V.W. van Hinsbergh, L.P. van Den Heuvel, and L.A. Monnens. (2001) "Detection of verocytotoxin bound to circulating polymorphonuclear leukocytes of patients with hemolytic uremic syndrome. <i>J Am Soc Nephrol</i> 12:800-806.
TS	CW	Thern, A., L. Stenberg, B. Dahlback, and G. Lindahl. (1995) "Ig-binding surface proteins of <i>Streptococcus pyogenes</i> also bind human C4b-binding protein (C4BP), a regulatory component of the complement system" <i>J Immunol</i> 154:375-386.
TS	CX	van den Berg, R.H., M. Faber-Krol, L.A. van Es, and M.R. Daha. (1995) "Regulation of the function of the first component of complement by human C1q receptor" <i>Eur J Immunol</i> 25:2206-2210.
TS	CY	Van den Graaf, F., J.A. Koedam, and B.N. Bouma. (1983) "Inactivation of kallikrein in human plasma" <i>J Clin Invest</i> 71:149-158.
TS	CZ	Waytes, A. T., Rosen, F. S. & Frank, M. M. (1996) "Treatment of Hereditary Angioedema with a Vapor-Heated C1 Inhibitor Concentrate" <i>N. Engl. J. Med.</i> 334(25):1630-1634.
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		Application Number	10/786,445
		Filing Date	February 25, 2004
		First Name Inventor	Rodney A. Welch
		Group Art Unit	1652
		Examiner Name	N/A
		Attorney Docket Number	096429-9141 US001

**U.S. PATENT DOCUMENTS**

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
TS	PCT	WO 02/34918	Wisconsin Alumni Research Foundation	May 2, 2002		

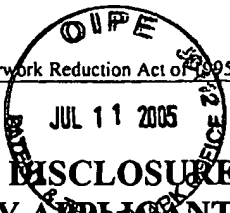
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number		10/786,445	
			Filing Date		February 25, 2004	
			First Named Inventor		Rodney A. Welch	
			Group Art Unit		1652	
			Examiner Name		N/A	
Sheet	1	of	1	Attorney Docket Number		096429-9141 US001

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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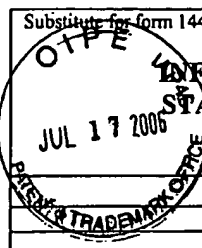
TS		Lathem et al., "A Novel Metalloprotease Secreted by <i>Escherichia coli</i> O157:H7 Cleaves C1 Esterase Inhibitor, a Regulator of Multiple Proteolytic Cascades," Abstract (2001) 101:113.

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 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 1 of 1		Application Number	10/786,445
		Filing Date	February 25, 2004
		First named Inventor	Rodney A. Welch
		Group Art Unit	1652
		Examiner name	Tekchand Saidha
		Attorney Docket Number	096429-9141-US00
<b>U.S. Patent Documents</b>			

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
TS	6,872,559	Welch et al.	3/29/2005

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract

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	TS	BRUNDER, W., "E. coli 3.3kb DNA fragment from plasmid p0157," Database EMBL 'Online! Database Entry EC33P0157, Y11831.1 (1999) 1-2
	TS	BRUNDER, W., "Hypothetical 34.0 kDa protein (Fragment)," Database SWALL 'Online! Entry number Q9ZAL1 (1999) 1
	TS	BURAK, K.W. et al., "C1 inhibitor deficiency and angioedema of the small intestine masquerading as Crohn's disease," Can. J. Gastroenterol (2000) 14(4):349-351
	TS	BURLAND, V. et al., "The complete DNA sequence and analysis of the large virulence plasmid of escherichia coli 0157:H7 plasmid p0157, complete sequence," Database EMBL 'Online! Database Entry AF074613 (1998) 1-54
	TS	GRYS, T.E. et al., "The StcE protease contributes to intimate adherence of enterohemorrhagic escherichia coli O157:H7 to host cells," Inf. Immun. (2005) 73(3):1295-1303
	TS	Sequence search alignment between Q9ZAL1 (5.1.1999) and SEQ ID No: 2 (residue 24-886)
	TS	WITOWSKI, S.E. et al., "StcE, a novel metalloprotease from enterohemorrhagic escherichia coli, is specific for p0157-containing strains of diarrheagenic E. coli," Abstracts of the General Meeting of the American Society for Microbiology, Washington DC (May 20-24, 2001) 101:113

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